

Docket No.: SYN-0007A



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Peter F.A. BAKKER et al.

Serial No.: 09/938,819

Filed: August 27, 2001

For: REFERENCE STANDARDS FOR DETERMINING THE PURITY OR STABILITY OF
AMLODIPINE MALEATE AND PROCESSES THEREFOR

: Group Art Unit: 1743

: Examiner: Cote

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Pursuant to 37 C.F.R. 1.56, the attention of the Patent and Trademark Office is hereby directed to the reference(s) listed on the attached PTO-1449. One copy of each reference is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the reference(s) be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the indicated date. Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered. This statement should not be construed as a representation that a search has been made, that information cited in the statement is considered to be and/or is material to patentability, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that was cited or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. §120. 1138 OG 37, 38 (May 19, 1992).

- X 1. This Information Disclosure Statement is being filed (i) within three months of the U.S. filing date of a U.S. application other than a CPA continued prosecution application under §1.53(d) OR (ii) within three months of the date of entry of the national stage as set forth in §1.491 in an international application OR (iii) before the mailing date of a first Office Action on the merits. No certification or fee is required. 37 C.F.R. §1.97(b).
- 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection OR Notice of Allowance OR an action that otherwise closes prosecution in the application. 37 C.F.R. §1.97(c).
- a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(1).

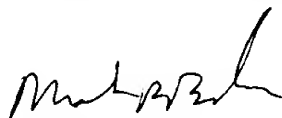
- b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(2).
- c. Attached is our check no. _____ in the amount of \$180.00 in payment of the fee under 37 C.F.R. 1.17(p). Please credit or debit Deposit Account No. 16-0607 as needed to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached.
- 3. This Information Disclosure Statement is being filed after the mailing date of a Final Rejection OR Notice of Allowance OR an action that otherwise closes prosecution in the application, but on or before payment of the Issue Fee. Attached is our check no. ____ in the amount of \$180.00 in payment of the fee under 37 C.F.R. 1.17(p). Please credit or debit Deposit Account No. 16-0607 as needed to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached. 37 C.F.R. §1.97(d).
- a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(1).
- b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(2).
- X 4. Applicants wish to bring to the Examiner's attention the existence of the following co-pending U.S. Patent Applications which are directed to related technical subject matter.

<u>Serial No.</u>	<u>Filed</u>	<u>Examiner</u>
09/938,820	August 27, 2001	Fan
09/938,821	August 27, 2001	Fan
09/938,817	August 27, 2001	Krass
09/938,818	August 27, 2001	Morris
09/938,816	August 27, 2001	Unknown
09/938,840	August 27, 2001	Fan
09/938,841	August 27, 2001	Fan
10/024,520	December 21, 2001	Unknown

A copy of each of the above-listed pending applications is attached hereto. The Examiner is requested to consider the above-listed applications in examination of the instant application. However, in as much as the applicants do not desire that the co-pending applications be printed on the face of any issued U.S. Patent, the applications have not been cited on a 1449 form. The identification of these U.S. Patent Applications is not to be construed as a waiver of secrecy as to any such application now or upon issuance of the present application as a patent.

- X 5. To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 16-0607 and please credit any excess fees to such deposit account.

Respectfully submitted,
FLESHNER & KIM, LLP



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Date: **June 26, 2002**

MLF/MRB:dbp

LIST OF PRIOR ART CITED BY APPLICANT (PTO-1449)				ATTY. DOCKET NO. SYN-0007A		APPLN. SERIAL NO. 09/938,819	
				APPLICANT(S) Peter F.A. BAKKER et al.			
				FILING DATE August 27, 2001		GROUP 1743	

U.S. PATENT DOCUMENTS							
EXAMINER'S INITIALS	*PATENT NO.	*ISSUE DATE	*INVENTOR NAME	CLASS	SUBCLASS	FILING DATE	
	4,879,303	11/07/89	Davison et al.				
	4,572,909	02/25/86	Campbell et al.				
	4,983,740	01/08/91	Peglion et al.				
	5,389,654	02/14/95	Furlan et al.				
	5,438,145	08/01/95	Furlan et al.				
	6,046,337	04/04/00	Bozsing et al.				
	5,155,120	10/13/92	Lazar et al.				

U.S. PATENT APPLICATION PUBLICATIONS						
	*PATENT APPLN. PUB. NO.	*PUB. DATE	*APPLICANT	CLASS	SUBCLASS	

U.S. PATENT APPLICATIONS						
	*APPLN. NO.	*FILING DATE	*INVENTOR	CLASS	SUBCLASS	

FOREIGN PATENT DOCUMENTS							
EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
						Yes	No
	0 244 944	01/24/90	EP				
	0 963 980 A2	12/15/99	EP				
	0 290 211 B1	09/04/91	EP				
	00/35910	06/22/00	WO				
	00/35873	06/22/00	WO				

OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)	
	Alker et al., "Long-acting dihydropyridine calcium antagonists. 9. Structure activity relationships around amlodipine", Eur J Med Chem (1991) 26, 907-913.
	Amlodipine Besylate Monograph, PHARMEUROPA Vol. 10, No. 2, 197-198, June 1998
	Faulkner et al., "Absorption of Amlodipine Unaffected by Food", Arzneim Forsch/Drug Res. 39 (11), No. 7, (1989)

EXAMINER	DATE CONSIDERED
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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U.S. PATENT APPLICATION PUBLICATIONS							
	*PATENT APPLN. PUB. NO.	*PUB. DATE	*APPLICANT	CLASS	SUBCLASS		
U.S. PATENT APPLICATIONS							
	*APPLN. NO.	*FILING DATE	*INVENTOR	CLASS	SUBCLASS		
FOREIGN PATENT DOCUMENTS							
EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
						Yes	No
	99/25688	05/27/99	WO				
	00/24714	05/04/00	WO				
	0 534 520 B1	03/19/97	EP				
	0 902 016 A1	03/17/99	EP				
	0 089 167 B1	10/15/86	EP				
	99/52873	10/21/99	WO				
OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)							
McDaid and Deasy, "Formulation development of a transdermal drug delivery system for amlodipine base", International Journal of Pharmaceutics 133 (1996) 71-83.							
Arrowsmith et al., "Long-Acting Dihydropyridine Calcium Antagonists. 1. 2-Alkoxymethyl Derivatives Incorporating Basic Substituents", J. Med. Chem. American Chemical Society, 1986, 29, 1696-1702.							
FDA FOIA Material on Amlodipine Besylate, NDA No. 19-787, "Review of an Original NDA", October 10, 1990.							
EXAMINER				DATE CONSIDERED			

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